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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,652	09/10/1999	PRAMOD K. SRIVASTAVA	8449-025-999	3088

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

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DATE MAILED: 03/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/393,652

Applicant(s)  
Srivastava et al.

Examiner  
G. R. Ewoldt

Art Unit  
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 18, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6-21, and 32 is/are pending in the application.
- 4a) Of the above, claim(s) 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 6-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11 20) ☐ Other:

#### DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Gerald Ewoldt, Art Unit 1644.

2. Applicant's note that Claim 21 is properly part of Group I is acknowledged. Said Claim has been rejoined with Group I.

New Claim 32 is drawn to a method employing a purified population of heat shock protein (HSP) - antigen complexes whereas the method under examination is drawn to a method employing a single HSP - antigen complex. Claims 32 is therefore withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Accordingly, Claims 1-2 and 6-21 are the subject of examination in this Office Action.

3. In view of Applicant's Amendment and Remarks, filed 12/18/01, all previous rejections have been withdrawn.

4. The following are new grounds for rejection.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the recitation of "the amount of heat shock protein present in the composition is in the range of 5  $\mu$ g to 5000  $\mu$ g", or "100  $\mu$ g or more," or "200  $\mu$ g or more," does not comprise a specific dosage or dosage range. A proper dosage is defined as a specific amount (or range) of a composition of a specific concentration (or range of concentrations). The recitation of an amount in the composition alone does not disclose the amount given the subject, thus the claim to an apparent administered dosage range is vague and indefinite.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-2 and 6-21 are rejected under 35 U.S.C. 103(a) each as being unpatentable over WO 95/15338 (1995, IDS) and U.S. Patent No. 5,993,803 (1999), in view of U.S. Patent No. 5,750,119 (1998) and Cohen (1992).

WO 95/15338 teaches a method of preventing or treating rejection of a grafted skin cell in a mammal comprising administering to the mammal a mammalian heat shock protein that is not hsp60 (cpn10) non-covalently bound to a peptide, that is not bacterial, after the cell is grafted (see particularly page 18, line 1 - page 19, line 6).

The reference teaching differs from the claimed invention in that it does not teach administration of the specific heat shock proteins gp96, hsp70, or hsp90, to a human, in the dosage ranges of 5  $\mu$ g to 5000  $\mu$ g, as well as administration before the cell is grafted.

The '803 patent teaches a method of preventing or treating rejection of a grafted skin cell in a mammal comprising administering to the mammal a mammalian heat shock protein (hsp60) non-covalently bound to a peptide, that is not bacterial, before or after the cell is grafted (see particularly page 18, line 1 - page 19, line 6).

The '119 patent teaches the similarity and interchangeability of heat shock proteins including hsp60, hsp70 and hsp90. Additionally the reference teaches that heat shock proteins non-covalently associate with peptides to form complexes.

Cohen teaches that heat shock proteins are highly conserved and related, and that they naturally bind unfolded proteins and peptides, hence the alternative name "chaperonins" (see particularly page 297, last paragraph - page 300, first paragraph).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of preventing or treating rejection of a grafted skin cell in a mammal comprising administering to the mammal a mammalian heat shock protein non-covalently bound to a peptide, that is not bacterial, after the cell is grafted, as taught by WO 95/15338 or the '803 patent, substituting gp96, hsp70, or hsp90 as the heat shock protein of the claimed method. One of ordinary skill in the art at the time the invention was made would have been motivated to make said substitution given the interchangeability of heat shock proteins as taught by the '119 patent and Cohen. Given the combined teachings of the prior art, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in achieving the claimed method given that two heat shock proteins cpn10 and hsp60 had been demonstrated by the prior art to reduce graft rejection. The substituting of equivalents for the same purpose has been repeatedly established as being obvious, see MPEP 2144.06. Note that neither WO 95/15338 nor the '803 patent specifically teach the treatment of humans, however, it is clear that both references intend to include human treatment within the scope of the teachings. See, for example, the cloning of human cpn10 in WO 95/15338 and the discussion of human HLA binding properties in the '803 patent. Further note that the optimization of dosage ranges (Claims 16-18) falls well within the purview of one of skill in the art and lends no patentable weight to the claimed invention.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

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Art Unit: 1644

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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Technology Center 1600  
March 5, 2002



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